IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO. _____

Bartle, C.J. May 24, 2007

Joy L. Banks ("Ms. Banks" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Milburn K. Banks, Ms. Banks' spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In November 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael S. Mancina, M.D., F.A.C.C. Based on an echocardiogram dated September 9, 2001, Dr. Mancina attested in Part II of Ms. Banks' Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on such findings,

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3(...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Mancina also attested that claimant had moderate aortic regurgitation. Ms. Banks' claim, however, does not present any
(continued...)

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $545,310.[5]

In the report of claimant's echocardiogram, Dr. Mancina stated that "[t]here is moderate mitral valve regurgitation; 26% of the left atrium is occupied by regurgitant flow during systole." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Mancina also stated that "[t]he left atrium is elongated and enlarged at 5.5 cm." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Dr. Mancina stated that claimant had an "estimated ejection fraction in the range of 61%," which does not meet the definition of a

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4(...continued)
of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve. Thus, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b).

reduced ejection fraction under the Settlement Agreement. See id.

In October 2002, the Trust forwarded the claim for review by Michael A. Rihner, M.D., one of its auditing cardiologists.[6] In audit, Dr. Rihner concluded that there was no reasonable medical basis for Dr. Mancina's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation.[7] Dr. Rihner determined that: "The mitral regurgitant jet area was overestimated. The mitral regurgitation is only mild (<20% of LAA)." Dr. Rihner also concluded that there was no reasonable medical basis for Dr. Mancina's finding of an enlarged left atrial dimension because: "The [left atrium] is normal in size <4.0 [cm] in the [antero-posterior] dimension and <5.0 in the supero-inf[erior] (I suspect they overestimated by including the

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6. In August 2002, the Trust issued a Tentative Determination Letter awarding Ms. Banks and her spouse Matrix A, Level II benefits, which claimant accepted. However, in October 2002, the Trust notified Ms. Banks that her claim had been selected for audit. Under the Settlement Agreement, the Trust and Wyeth could each designate for audit a certain number of claims for Matrix Benefits and identify the condition(s) to be reviewed during the audit. See Settlement Agreement § VI.F; Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. In Pretrial Order ("PTO") No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

7. Dr. Rihner noted that claimant's echocardiogram was dated September 10, 2001, instead of September 9, 2001. The parties do not dispute that Dr. Rihner reviewed claimant's correct echocardiogram.

pulmonary veins in their tracing of the LA)." Dr. Rihner was not asked to review claimant's ejection fraction. In the audit worksheet, however, Dr. Rihner checked the box for an ejection fraction in the range of 50% to 60%. Dr. Rihner did not elaborate. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. at § IV.B.2.c.(2)(b).

Thereafter, the Trust issued a post-audit determination denying Ms. Banks' Matrix Benefits claim.[8] Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457 (May 31, 2002), Audit Policies and Procedures § VI. The Trust then applied to the court for issuance of an Order to show cause why Ms. Banks' claim should be paid.[9] On November 2, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4099 (Nov. 2, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

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8. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claimant is entitled to Matrix Benefits.

9. Although Ms. Banks disputed the Trust's post-audit determination in February 2003, the Trust did not file its Application until August 2004 because, according to the Trust, Ms. Banks' claim "was misdirected within the Trust until it was brought to the attention of Trust personnel in August, 2004."

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 10, 2005. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. § VI.O.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and an abnormal left atrial dimension, and whether she can establish a reasonable medical basis for a reduced ejection fraction based on the auditing cardiologist's finding. See id. § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form at issue, we must confirm

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. See id.

the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Banks submitted an additional report based on her September 9, 2001 echocardiogram and a verified expert opinion from Robert L. Rosenthal, M.D. In the echocardiogram report, Dr. Rosenthal quantified claimant's RJA/LAA ratio as 28%, measured claimant's left atrial dimension at 3.0 cm in the parasternal long axis view and 5.4 cm in the apical four chamber view, and estimated claimant's ejection fraction as 55%.[11] In his expert opinion, Dr. Rosenthal stated that:

> The degree of mitral regurgitation is $\geq$ 20% with multiple jets recorded which meet this criterion. The maximal jet is 5.12 cm^2 recorded at 16:59:20 recording time. This is an appropriately colored mosaic Doppler jet emanating from the mitral valve in systole. The left atrial area is drawn appropriately at 16.32 cm^2 giving a RJA/LAA of 31%. . . .
>
> The auditing cardiologist does not dispute the presence of depressed left ventricular function.
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> The auditing cardiologist contests the presence of left atrial enlargement indicating that the pulmonary vein was included in the tracing. I do not believe

11. Dr. Rosenthal's report is titled "Limited Fen-Phen Echocardiogram Study" and includes a disclaimer that states: "Interpretation of this study by the above named physician does not constitute a Doctor/Patient relationship."

> the pulmonary vein is included in the tracing which appropriately depicts the maximal apical dimension of the left atrial chamber consistent with Green Form page 27.

Claimant also argues that: (1) the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational or senseless from any medical perspective" and that an opinion lacks a reasonable medical basis only when it is "so slanted as to exist outside of the 'present state of science;'" (2) Dr. Rosenthal's findings support a reasonable medical basis for her claim; (3) under the Settlement Agreement, the auditing cardiologist was required to provide a specific measurement as to the level of regurgitation; and (4) "[t]he Auditing Cardiologist acknowledged that the complicating factor of a reduced ejection fraction is present."

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard and argues that a claim cannot be supported by a reasonable medical basis where the attesting physician overestimated the mitral regurgitant area and overestimated the left atrium by including the pulmonary vein. The Trust also argues that Dr. Rihner complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. The Trust further asserts that claimant's expert, Dr. Rosenthal, based his findings of moderate mitral regurgitation on a single, non-representative still frame, which is not permitted under the Settlement

Agreement.[12] Finally, the Trust argues that claimant cannot establish that she had a reduced ejection fraction based on the auditing cardiologist's finding because claimant failed to "assert the presence of an ejection fraction less than or equal to 60% on the Green Form."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

> In reviewing the transthoracic echocardiogram, my visual estimate is that there is moderate mitral regurgitation. The color gain settings were set too high, so I measured the RJA/LAA ratios to [e]nsure that the gain settings did not lead me to overestimate the ratio. I measured the mitral regurgitant jet in three different cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are 5.27 cm^2/21.35 cm^2, 4.43 cm^2/19.23 cm^2, and 4.48 cm^2/18.96 cm^2. These ratios are 24.7%, 23.0% and 23.6%, all of which are greater than 20% which is consistent with moderate mitral regurgitation.

Dr. Abramson, however, concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Dr. Abramson measured

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12. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).

claimant's left atrial dimension as 3.3 cm in the parasternal long axis view and 4.9 cm in the apical four chamber view. She further determined that "[t]he measurement of the left atrium on the tape is taken off-axis which accounts for the erroneously large measurement mentioned in the echo reports."

Dr. Abramson also concluded that there was no reasonable medical basis for finding that claimant had a reduced ejection fraction in the range of 50% to 60%. As explained by Dr. Abramson:

> The ejection fraction in this patient is >60% and within normal limits. All walls are contracting normal. I measured three ejection fractions of 65%, 68% and 69% using the Simpson's method of discs. All of these measurements are clearly greater than 60%.

In response to the Technical Advisor Report, claimant submitted a one-paragraph letter, arguing that she is entitled to Matrix A-1, Level II benefits based on the findings of the Technical Advisor and auditing cardiologist. Claimant contends that, as the Technical Advisor found moderate mitral regurgitation and the auditing cardiologist found a reduced ejection fraction, she is entitled to Matrix Benefits.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusions, Dr. Abramson confirmed that claimant

suffers from moderate mitral regurgitation.[13] Specifically, Dr. Abramson stated that "there is a reasonable medical basis for the Attesting Physician to state that this Claimant has moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Abramson found that moderate mitral regurgitation was visible throughout the echocardiogram by visual inspection. She then measured three different cardiac cycles to confirm her visual evaluation and found that the RJA/LAA ratios were all above the 20% threshold. Under these circumstances, there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.[14]

However, we find that there is no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. First, and of crucial importance, claimant does not contest the analysis provided by the Technical Advisor. Claimant does not challenge Dr. Abramson's conclusion that claimant's left atrial dimension was normal, measuring 3.3 cm in the parasternal long axis view and 4.9 cm in the apical four chamber view. Nor does claimant refute Dr. Abramson's

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13. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

14. Accordingly, we need not address claimant's remaining arguments regarding mitral regurgitation.

determination that "[t]he measurement of the left atrium on the tape is taken off-axis which accounts for the erroneously large measurement mentioned in the echo reports." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her attesting physician's finding of an abnormal left atrial dimension.

We also disagree with claimant's definition of reasonable medical basis. Without any discussion, claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. The word "unreasonable" does not always mean "irrational," as claimant would have us believe.

We are not persuaded that either Gallagher or Black's supports claimant's position as to the definition of "reasonable medical basis." Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis.

Moreover, a claimant cannot establish a reasonable medical basis for his or her claim simply by supplying opinions of additional cardiologists. This is especially true where, as here, claimant has failed to address adequately the improper practices underlying the attesting physician's finding of an abnormal left atrial dimension.

Finally, we disagree with claimant that she has met her burden in establishing the complicating factor of a reduced ejection fraction. Her attesting physician measured her ejection fraction as 61%, which does not meet the definition for a reduced ejection fraction under the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although claimant now seeks to use the finding of her reviewing cardiologist, Dr. Rosenthal, that claimant had an ejection fraction of 55%, neither claimant nor Dr. Rosenthal explains the discrepancy between Dr. Rosenthal's finding and the initial Green Form answer. We simply cannot allow a "changed" Green Form attestation without any explanation by the attesting physician, Dr. Mancina, particularly where the "changed answer" is inconsistent with the echocardiogram report for the echocardiogram at issue in the Green Form. Equally significant, the Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that claimant had a reduced ejection fraction. Dr. Abramson measured three ejection fractions of 65%, 68% and 69%, all of which are clearly greater than 60%. Claimant did not directly refute these specific

findings. For all of these reasons, therefore, claimant has not met her burden in establishing a reasonable medical basis for finding that claimant has a reduced ejection fraction.[15]

Accordingly, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis to conclude that she had an abnormal left atrial dimension or an ejection fraction in the range of 50% to 60%. Therefore, we will affirm the Trust's denial of Ms. Banks' claim for Matrix benefits and the related derivative claim submitted by her husband.

15. For these reasons as well, we also find that, in these circumstances, claimant cannot rely on the auditing cardiologist's worksheet to establish a reasonable medical basis for a reduced ejection fraction, as the auditing cardiologist merely checked the box on the audit worksheet for an ejection fraction in the range of 50% to 60%, without providing any explanation.

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PRETRIAL ORDER NO.

AND NOW, on this 24th day of May, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and the Level II Matrix claims submitted by claimant, Joy L. Banks, and her spouse, Milburn K. Banks, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.